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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/692,245

10/19/2000

Harry F. Prest

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10/22/2003

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EXAMINER

LUDLOW, JAN M

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/692,245

Applicant(s)

PREST

Examiner

Jan M. Ludlow

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 December 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 28, 2003 has been entered.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

3. A person shall be entitled to a patent unless –

4. (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

a. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to

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which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

7. Determining the scope and contents of the prior art.
8. Ascertaining the differences between the prior art and the claims at issue.
9. Resolving the level of ordinary skill in the pertinent art.
10. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al.

12. Lee et al teaches derivatization of de-polymerized polymers with TMS, followed by GC analysis (col. 9, lines 20, 38 and col. 10, lines 25-40). Glucose is identified by retention time and peak area ratios of the alpha and beta anomers, the alpha and beta anomers constituting the instant two derivatives.

13. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenfeld.

14. Rosenfeld teaches a method of analyzing prostaglandin E2 (PGE2) using PFBBr and PFBHOX derivatizing agents in situ on a column. Samples are then subjected to gas chromatography and electron capture and the trace shown in Figure 8. Two peaks are labeled PGE2, indicating that two derivatives are present. It is the examiner's position that the X-axis on the chromatographic trace is time because the beginning and end of the axis are labeled "start" and "stop" which indicate reference to time. See Example 16. Rosenfeld additionally teaches separation of derivatives of THC formed

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metabolically and further derivatized in situ (Figures 4A-4B). Rosenfeld additionally teaches that Mass Spec analysis can be used in place of Electron Capture (EC) in the PGE2 analysis (col. 19, lines 25-26) and that MS typically includes negative ion chemical ionization mode (col. 1, lines 25-30).

15. Rosenfeld fails to explicitly teach determining retention times, ionizing derivatized analytes or mass spec using negative chemical ionization for the PGE2 or THC analyses, or using peak ratios to determine quantity.

16. Cook et al teaches that similar compounds can be used as internal standards for each other in chromatographic analyses, and that area ratios of two similar compounds can be used to quantify (col. 10, lines 33-50).

17. It would have been obvious to determine retention times in order to identify peaks as shown in the Figures and as was known in the art. It would have been obvious to ionize the derivatized analytes in order to perform EC, Mass Spec or Mass Spec with negative ion chemical ionization mode in order to perform the analyses taught or suggested by Rosenfeld for detecting and quantifying the derivatized analytes. It is the examiner's position that prostaglandin constitutes a drug of abuse because it is a hormone-like substance that may be used improperly. With respect to specific drugs of abuse other than THC and prostaglandin, and derivatizing agents other than those disclosed by Rosenfeld, Rosenfeld teaches that the method is widely applicable to drug, herbicide and pesticide residues (col. 7, lines 28-32) and it would have been obvious to perform the method on the claimed classes of compounds as known drugs, using known classes of derivatizing agents. It would have been further obvious to use peak

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ratios of the similar compounds to identify and/or quantify the similar compounds as taught by Cook.

18. Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

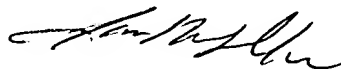
20. Mee et al teaches comparison of MS peaks between derivatized compounds and analogs, but teaches chromatographic separation as unnecessary (col. 5, lines 50-55).

21. Kanai teaches that reaction product purity can be determined from peak area ratios of HPLC separated starting material, product and byproducts (col. 8, lines 8-17).

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

Jml
October 19, 2003